



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,394	01/25/2005	Yoshiharu Sato	10921.0272USWO	6311

52835 7590 08/11/2008
HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. BOX 2902
MINNEAPOLIS, MN 55402-0902

EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
----------	--------------

1795

MAIL DATE	DELIVERY MODE
-----------	---------------

08/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,394	Applicant(s) SATO ET AL.	
	Examiner KAJ K. OLSEN	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10-12 is/are allowed.
- 6) ☒ Claim(s) 1,2 and 13-16 is/are rejected.
- 7) ☒ Claim(s) 3-9, 17-19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The objection to the disclosure has been withdrawn in view of the amendment.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 2002/44705 (hereafter “WO ‘705”). For this rejection, the examiner is relying on the English language disclosure of Miyazaki et al (USP 7,232,510). All cited column and line numbers below refer to locations within the text of Miyazaki.
4. With respect to claim 13, JP ‘705 discloses a sample analyzer comprising a voltage applier for application of a voltage to a reaction field (col. 9, ll. 18-23), a response measurer for measurement of a response to the voltage applied to the reaction field (col. 9, ll. 24-45), a selector for selecting a first voltage application state for measurement of a first response for use in a calculation necessary for analyzing the sample (S8 of fig. 5, see also the discussion above), and a second voltage application state for measurement of a second response for use in determining whether or not the reaction field has been supplied with a target amount of the sample (see fig. 6, col. 12, ll. 28-46 and col. 13, ll. 15-38). JP ‘705 further discloses an

arithmetic operator 25 for calculation necessary for analyzing the sample based on the first response (col. 13, ll. 46-57) and a determiner for determination based on the second response on whether or not the reaction field has been supplied with the target amount of sample (see col. 12, ll. 28-46 and col. 13, ll. 15-38) and a controller for causing the selector to select the second voltage application state after causing the selector to select the first voltage application state (i.e. the first step in fig. 5 is programmed to occur before the second step in fig. 6).

5. With respect to the new limitation drawn to when the selector is to be utilized, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability.

6. With respect to claim 14, WO '705 monitors the signals coming from the various electrodes as currents that are subsequently converted into voltage signals by the current/voltage converter 23. See col. 9, ll. 24-45.

7. With respect to claim 15, WO '705 utilizes electrodes leads A and F for the first response and either leads A and C, or leads A and E, for the second response. See fig. 5 and 6. Hence WO '705 relies on differing electrode combinations.

8. With respect to claim 16, see fig. 4 and col. 9, ll. 20-23.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 2, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1 074 832 (hereafter “EP ‘832”) in view of Genshaw et al (USP 5,620,579). EP ‘832 was previously cited, but is being relied on for the first time with this office action. Genshaw is being cited and relied on for the first time with this office action. The use of EP ‘832 and Genshaw was necessitated by applicant’s amendment to the claims.

11. EP ‘832 discloses a sample analyzing method based on a response obtained upon application of a voltage to a reaction field containing a sample. Said method comprises a preliminary step for introducing the sample (blood) to the reaction field followed by three current measurements I_{b10} , I_{r5} , and I_{r10} . See paragraph 0014. Either of currents I_{b10} or I_{r5} would read on the claimed “first step” while either or I_{r5} or I_{r10} would read on the claimed “second step” that is performed later than either of the possible first steps. EP ‘832 further discloses that the currents I_{r5} and I_{r10} for this second step can be utilized as part of a calculation to determine whether a target amount of sample has been supplied to the reaction field (i.e. whether the sample was a short fill). See col. 7, l. 30 - col. 8, l. 32. EP ‘832 did not explicitly disclose how the calculation for analyzing the sample was done. Hence, EP ‘832 does not explicitly disclose that either of the first responses were to be utilized in a calculation necessary for analyzing the sample. However, Genshaw from the same assignee as EP ‘832 teaches that the sample is analyzed utilizing a combination of currents i_1 (equivalent to I_{b10} in EP ‘832) and currents i_2 (equivalent to I_{r5} and I_{r10} in EP ‘832). See fig. 1A and 3 and col. 6, l. 17 - col. 7, l. 50. Hence, Genshaw teaches the use of currents equivalent to the first response currents of I_{b10} and I_{r5} from EP ‘832 for use in a calculation necessary for analyzing the sample. It would have been obvious to one of ordinary

skill in the art at the time the invention was being made to utilize the teaching of Genshaw for the method of EP '832 so that the monitored currents can be utilized to determine the analyte concentration, which is the stated goal of EP '832 (see claim 1).

12. EP '832 also discloses a sample analyzer comprising a voltage applier for application of a voltage to a reaction field including a sample, and a response measurer for measurement of a response to the voltage. EP '832 further discloses three separate response measurements I_{b10} , I_{r5} , and I_{r10} that each having voltage application states affiliated with them. The voltage applied for the measurement of either I_{b10} or I_{r5} would read on the defined first voltage application state while the voltage applied during the measurement of either I_{r5} or I_{r10} would read on the defined second voltage application state. EP '832 further discloses a determiner for determination based on either of the second responses, on whether or not the reaction field has been supplied with the target amount of sample (i.e. the sample is not a short fill). See col. 7, l. 30 - col. 8, l. 32 and note that either I_{r5} or I_{r10} can be utilized for the determination of the short fill. EP '832 does not describe how the analyte measurement is to be performed, so EP '832 does not explicitly disclose an arithmetic operator for calculation necessary for analyzing the sample based on the first response. However, Genshaw from the same assignee as EP '832 teaches that the sample is analyzed utilizing a combination of currents i_1 (equivalent to I_{b10} in EP '832) and currents i_2 (equivalent to I_{r5} and I_{r10} in EP '832). See fig. 1A and 3 and col. 6, l. 17 - col. 7, l. 50. Hence, Genshaw teaches the use of currents equivalent to the first response currents of I_{b10} and I_{r5} from EP '832 for use in an arithmetic calculation necessary for analyzing the sample. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize

the teaching of Genshaw for the analyzer of EP '832 so that the monitored currents can be utilized to determine the analyte concentration, which is the stated goal of EP '832 (see claim 1).

Allowable Subject Matter

13. Claims 10-12 are allowed.

14. Claims 3-9 and 17-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter: The allowable subject matter of claims 6-12 and 17-19 can be found in the previous office action. With respect to claims 3-5, the prior art does not disclose nor render obvious the cumulative limitations of claims 1 and 3 with particular attention to the combination of electrodes selected in the first step differing from a combination of electrodes selected in the second step.

Response to Arguments

16. Applicant's arguments with respect to claims 1-3 have been considered but are moot in view of the new ground(s) of rejection.

17. Applicant's arguments with respect to claims 13-16 and WO '705 have been fully considered but they are not persuasive. Applicant urges that the analyzer of claim 13 is free of WO '705 for the same reason that method claim 1 is free of this teaching. However, applicants

amendment to claim 13 is merely reciting the intended use of the selector and the intended use need not be given further due consideration in determining patentability.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAJ K. OLSEN whose telephone number is (571)272-1344. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number:
10/522,394
Art Unit: 1795

Page 8

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kaj K Olsen/
Primary Examiner, Art Unit 1795
August 12, 2008